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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,607	12/08/2000	Giulio Tononi	P-NI 4447	4199

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EXAMINER	
HOLBROOK, PAMELA G	

ART UNIT	PAPER NUMBER
1647	9

DATE MAILED: 01/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/733,607	TONONI ET AL.	
	Examiner	Art Unit	
	Pamela G Holbrook	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 October 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 7-9, drawn to polynucleotides classified in class 536, subclass 23.5.

II. Claims 3-6, drawn to oligonucleotides, classified in class 536, subclass 24.33.

III. Claims 10 and 11, drawn to methods to diagnose vigilance disorders by determining vigilance level, classified in class 435, subclass 6.

IV. Claims 12 and 13, drawn to methods to screen for compounds to treat vigilance disorders, classified in class 435, subclass 6.

V. Claims 14 and 15, drawn to methods to treat vigilance disorders by modulating vigilance level, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to completely different

products having completely different structures and biological functions which are not interchangeable and which require non-cohesive searches and considerations. Since the oligonucleotides of the invention of group II are derived from the full length polynucleotides of the invention of group I these two products can not be used together. The oligonucleotides could hybridize with the polynucleotides rendering them ineffective templates.

3. Inventions III – V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different disclosed effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to completely different method steps, using different compositions and having completely different outcomes. The invention of group III drawn to methods to diagnose vigilence disorders by monitoring vigilance gene profiles requires a step to measure vigilance gene profiles but does not require the compounds of the invention of group IV drawn to screening methods nor does it require a step to measure therapeutic outcome as does the invention of group V drawn to methods to treat vigilance disorders. The invention of group IV requires, in addition to the method to measure vigilance gene profiles of the invention of group III, compounds to be screened and does not require the step to measure therapeutic outcome of the invention of group V. The invention of group V drawn to a methods to treat vigilance disorders does not require the compounds of the invention of group IV and requires, in addition to

a step to measure vigilance gene profiles or the invention of group III, a step to measure therapeutic outcome.

4. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: 1) the process for using the product as claimed can be practiced with another materially different product or 2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the vigilance polynucleotide can be used in a materially different process, such as making the vigilance protein.

5. Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: 1) the process for using the product as claimed can be practiced with another materially different product or 2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the vigilance polynucleotide can be used in a materially different process, such as making the vigilance protein.

6. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: 1) the process for using the product as claimed can be practiced with another materially

different product or 2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the vigilance polynucleotide can be used in a materially different process, such as making the vigilance protein.

7. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: 1) the process for using the product as claimed can be practiced with another materially different product or 2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotide can be used in a materially different process, such as PCR.

8. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: 1) the process for using the product as claimed can be practiced with another materially different product or 2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotide can be used in a materially different process, such as PCR.

9. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: 1) the process for using the product as claimed can be practiced with another materially

different product or 2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the oligonucleotide can be used in a materially different process, such as PCR.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

11. Because these inventions are distinct for the reasons given above and the literature search required for any single group is not required for any other group, restriction for examination purposes as indicated is proper.

12. Restriction to one of the following inventions is also required under 35 U.S.C. 121:

Inventions 1–27 as they pertain to SEQ ID NO: 1 - SEQ ID NO: 27 respectively.

13. The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOS: 1-27 is a unique sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on

the examiner and the USPTO's resources because of the non-coextensive nature of these searches. Each of the sequences represents a novel structure with a potentially different pharmaceutical property.

14. Because these inventions are distinct for the reasons given above and the search required for any single group is not required for any other group, restriction for examination purposes as indicated is proper.

15. **In order to be fully responsive, Applicant must select one from Groups I-V, and one from 1-27. Applicant is advised that neither I-V nor 1-27 are species election requirements; rather, each of I-V and 1-27 is a restriction requirement.**

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pamela Holbrook whose telephone number is (703) 306-3221, Mon.- Fri. 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623

The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [gary.kunz@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 21, 2001

Gary L. Kunz

GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600